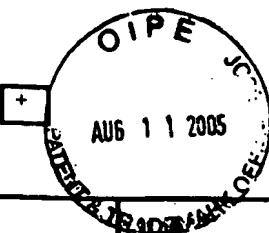


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			First Named Inventor	PIZZA et al.	
			Group Art Unit	1642	
			Examiner Name	Unassigned	
Sheet	1	of	3	Attorney Docket Number	PP000338.0105 (2300-0338.02)

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code <sup>2</sup> (if known)		
A1	A1	5,182,109		Tamura, et al.	01-26-1993

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		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)			
B1	B1	WO	95/09649		MEDEVA HOLDINGS B.V.	04-13-1995	
B2	B2	WO	95/34323		CONNAUGHT LABORATORIES LIMITED	12-21-1995	
B3	B3	WO	96/06627		THE ADMINISTRATORS OF THE TULANE EDUCATIONAL FUND	03-07-1996	
B4	B4	WO	99/58145		UNIVERSITY OF BRISTOL	11-18-1999	
B5	B5	WO	00/18434		AMERICAN CYNAMID COMPANY	04-06-2000	
B6	B6	EP	0396964		SCLAVO S.P.A.	11-14-1990	
B7	B7	EP	0462534		SCLAVO S.P.A.	12-27-1991	
B8	B8	GB	9320454.3		MEDEVA HOLDINGS B.V		
B9	B9	GB	9324743.5		MEDEVA HOLDINGS B.V		

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OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	C1	Bumette, "The Advent of Recombinant Pertussis Vaccines." <i>Biotechnol.</i> 8:1002-1005 (1990)
	C2	Bumette, <i>Vaccine Research &amp; Developments</i> Marcel Dekker Inc., New York, New York (1992)
	C3	Clements, et al., "Adjuvant Activity of Escherichia Coli Heat-Labile Enterotoxin and Effect on the Induction of Oral Tolerance in Mice to Unrelated Protein Antigens." <i>Vaccine</i> 6:269-277 (1988)
	C4	Communication to EPO Concerning Replacement Claims for Filing with the EPO in Application No. 99922284.7 (2003)
	C5	de Haan, et al., "Mutational Analysis of the Role of ADP-Ribosylation Activity in the Adjuvant Properties of the Escherichia Coli Heat-Labile Enterotoxin Towards Intranasally Administered Keyhole Limpet Hemocyanin." <i>Eur. J. Immunol.</i> 28:1243-1250 (1998)
	C6	Del Guidice, et al., "Genetically Derived Toxoids for use as Vaccines and Adjuvants." <i>Vaccine</i> 17:S44-S52 (1999)
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	C9	EPO Communication pursuant to Article 96(2) EPC relating to Application EP No. 94928455.8-2116 (2001)
	C10	"Multicomponent Vaccine Development." <i>NIH Guide</i> Volume 22, Number 28 (1993)
	C11	Green, Bruce, Curriculum Vitae
	C12	Hagen, Michael, Curriculum Vitae
	C13	Hagiwar, et al., Effectiveness and Safety of Mutant Escherichia Coli Heat-Labile Enterotoxin (LT H44A) as an Adjuvant for Nasal Influenza Vaccine." <i>Vaccine</i> 19:2071-2079 (2001)
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	C25	<i>The Comprehensive Sourcebook of Bacterial Protein Toxins</i> , 2 <sup>nd</sup> Ed., Academic Press, pgs. 696-697
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
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[Signature]	A1	4,328,209		Finkelstein et al.	5/4/82
	A2	4,666,837		Harford et al.	5/19/87
	A3	4,935,364		Kaper et al.	6/19/90
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	A7	6,019,982		Clements et al.	2/1/00
	A8	6,033,673		Clements	3/7/00
	A9	6,149,919		Domenighini et al.	11/00

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	B1	WO	92/19265			11/12/92	
	B2	WO	93/13202		Domenighini	7/8/93	

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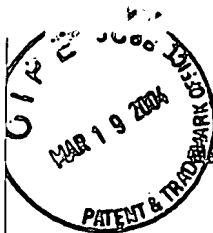
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OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS		
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	C1	BOSLEGO, J.W. et al., Vaccines and Immunotherapy, Chapter 17, 1991, 211-223
	C2	BURNETTE, W.N. et al., "Site-specific mutagenesis of the catalytic subunit of cholera toxin: substituting lysine for arginine 7 causes loss of activity," <i>Inf. &amp; Immun.</i> , 1991, 59:4266-4270
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	C9	FONTANA, M.R. et al., "Construction of nontoxic derivatives of cholera toxin and characterization of the immunological response against the A subunit," <i>Infection and Immunity</i> , 1995, 63(6):2356-2360
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	C12	HARFORD, S. et al., "Inactivation of the <i>Escherichia coli</i> heat-labile enterotoxin by in vitro mutagenesis of the A-subunit gene," <i>Eur. J. Biochem.</i> , 1989, 183:311-316
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C25	MAGAGNOLI, C. et al., "Mutations in the A subunit affect yield, stability, and protease sensitivity of nontoxic derivatives of heat-labile enterotoxin," <i>Infection and Immunity</i> , 1996, 64(12):5434-5438
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